

In the Claims:

Applicants respectfully request that the existing claims identified below be amended as follows, that claims 61-105 be added and claims 19, 31 and 59 be cancelled without prejudice, to further define and claim the invention.

Claim 1 (Once amended) A method for delivering a therapeutic gas to a [patient] person having a [mouth and a nose] nasal mucous membrane, said method comprising:

generating a flow of a therapeutic gas; and

infusing [a nasal and/or an oral] the nasal mucous membrane with the flow of therapeutic gas; wherein the [patient] person refrains from inhaling.

Claim 3 (Once amended) A method as in claims 1[or], 2, 61 102 or 103, wherein the therapeutic gas is selected from the group consisting of carbon dioxide, nitric oxide, oxygen, helium, dilute mixtures of nitric oxide, and isocapnic mixtures of acid gases.

Claim 5 (Once amended) A method as in claim 3, wherein the [carbon dioxide] therapeutic gas is present in a carrier gas.

Claim 6 (Once amended) A method as in claim 3, wherein generating comprises generating a flow at a rate in the range from 0.5 cc/sec to 20 cc/sec [carbon dioxide] of therapeutic gas.

Claim 11 (Once amended) A method as in claims 10 or 102, wherein the [patient] person's mouth is closed and the flow [exists] exits entirely from the other nostril.

Claim 16 (Once amended) A method for generating a therapeutic dosage of [a] gas, said method comprising:

Releasing from a hand-held dispenser a flow of [therapeutic] treatment gas comprising from 0.5 cc/sec to 20 cc/sec, when the treatment gas comprises a therapeutic gas is selected from the group consisting of carbon dioxide, nitric oxide, oxygen, helium, dilute mixtures of nitric

oxide, and isocapnic mixtures of acid gases.

Claim 19 Cancelled without prejudice.

Claim 20 (Once amended) A method as in claim [19] 16 wherein the [carrier] treatment gas further comprises a therapeutic gas and a gas selected from the group consisting of air, oxygen, nitrogen, and halogenated hydrocarbons.

Claim 27 (Once amended) A method as in claim 16, wherein releasing comprises adjusting the flow rate to [a set point] within the 0.5 cc/sec to 20 cc/sec range.

Claim 28 (Once amended) A dispenser for delivering a therapeutic agent in the form of a gas, said [method] dispenser comprising:

a container holding a volume of the therapeutic [gas] agent under pressure;
a flow regulator that releases a flow of the [therapeutic] gas from the container; and
an outlet [that seals against] through which the flow of the gas is released, said outlet sealable with a human [nostril] facial orifice.

Claim 29 (Once amended) A dispenser as in claim 28, wherein the therapeutic agent [gas] is selected from the group consisting of carbon dioxide, nitric oxide, oxygen, helium, dilute mixtures of nitric oxide, and isocapnic mixtures of acid gases [with a carrier gas].

Claim 30 (Once amended) A dispenser as in claim 29, wherein the therapeutic agent [gas] consists essentially of carbon dioxide.

Claim 31 Cancelled without prejudice.

Claim 32 (Once amended) A dispenser as in claim 28, wherein the therapeutic [gas] agent

comprises carbon dioxide in a carrier gas.

Claim 34 (Once amended) A dispenser as in claim 33, wherein the container [comprises a cylinder] defines a first end and a second end, the adjustable flow regulator comprises a head at [one] the first end of the [cylinder,] container and the outlet comprises a nozzle in the head.

Claim 35 (Once amended) A dispenser as in claim 34, wherein the head is axially translatable and carries a needle that perforates a sealing cap in the first end of the [cylinder] container to form a flow-regulating orifice in the cap.

Claim 36 (Once amended) A dispenser as in claim 34, wherein the head is axially translatable and carries a needle that perforates a sealing cap in the first end of the [cylinder] container, to form an orifice in the cap, wherein flow is controlled by a previously formed orifice in the [head] adjustable flow regulator.

Claim 48 (Once amended) A dispenser as in claim 39, wherein the container [comprises] defines a first end and a second end [cylinder,] and the adjustable flow regulator comprises a head at [one]the first end of the [cylinder] container, and the outlet comprises a nozzle in the head.

Claim 50 (Once amended) A dispenser as in claim 48, wherein the head is axially translatable and carries a needle that perforates a sealing cap in the [cylinder] container, wherein flow is controlled by a previously-formed orifice in the [head] flow regulator.

Claim 53 (Once amended) A kit comprising:

A container holding a therapeutic agent [gas]; and

Instructions for use setting forth a method for delivering the therapeutic agent [gas] to a [patient] person from the container comprising:

generating a flow of the therapeutic agent in the form of a gas; and

directing the flow into a facial orifice of the person while the person refrains from inhaling the therapeutic gas, whereby a mucous membrane is infused with the gas [infusing a nasal and/or and oral mucous membrane with the flow of therapeutic gas,
wherein the [patient] person refrains from inhaling the therapeutic gas].

Claim 54 (Once amended) A kit comprising:

A hand-held container holding carbon dioxide; and

Instructions for use setting forth a method for delivering the carbon dioxide from the container to a [patient] person comprising:

Releasing from the hand-held container a flow of carbon dioxide comprising from 0.5 cc/sec to 20 cc/sec of carbon dioxide.

Claim 55 (Once amended) A [container] kit as in claim 54 wherein the instructions further set forth to direct the carbon dioxide to a nostril or mouth of the [patient] person while the [patient] person refrains from inhaling the carbon dioxide.

Claim 58 (Once amended) A kit comprising:

a container holding a therapeutic [gas] agent; and

instructions for use setting forth a method for delivering the therapeutic [gas] agent to a [patient] person from the container comprising;

generating a flow of the therapeutic [gas] agent in the form of a gas; and
infusing an ocular mucous membrane with the flow of [therapeutic] gas.

Claims 59 Cancelled without prejudice.

Claim 60 (Once amended) A gas dispensing needle as in claim [59] 100, wherein the [penetrating tip] first region extends between [over a length in the range from 0.6 mm to 1 mm] 0.2 mm to 0.6 mm from the penetrating tip and the [conical shaft] second region extends between [over a length in the range of 0.2 mm to 0.6 mm] 0.6 mm to 1 mm from the penetrating tip.

Claim 61 (New) A method for delivering a therapeutic gas to a person having an oral mucous membrane, trachea and lung, said method comprising:

generating a flow of a therapeutic gas; and

infusing the oral mucous membrane with the flow of therapeutic gas; wherein the person substantially inhibits the passage of the therapeutic gas into the trachea and lung by limiting inhalation of the therapeutic gas.

Claim 62 (New) A method as in claim 4, wherein the carbon dioxide is present in a carrier gas.

Claim 63 (New) A method as in claim 4, wherein the carbon dioxide is present in at least one carrier gas.

Claim 64 (New) A dispenser as in claim 48, wherein the head further comprises: a needle that perforates a sealing cap in the container to form an orifice of a preselected diameter and wherein the needle is axially translatable; a spring engaged with the needle that holds the needle in the orifice; a lever attached to the needle such that operation of the lever lifts the needle from the orifice and compresses the spring, whereby the gas is released through the outlet.

Claim 65 (New) A method as in claim 4, wherein generating comprises generating a flow at a rate in the range from 0.5 cc/sec to 20 cc/sec of carbon dioxide.

Claim 66 (New) A method as in claim 65, wherein the gas flow is continued for from 1 to 100 seconds.

Claim 67 (New) A method as in claim 66, further comprising at least a second infusing step which is continued for from 1 to 100 seconds.

Claim 68 (New) A method as in claim 67, further comprising at least a third infusing step which is continued for from 1 to 100 seconds.

Claim 69 (New) A method as in claim 16, wherein the carrier gas is inert.

Claim 70 (New) A method as in claim 16, wherein the carrier gas is biologically active.

Claim 71 (New) A method as in Claim 19, wherein the carrier gas is inert.

Claim 72 (New) A dispenser as in Claim 28, wherein the orifice is a nostril.

Claim 73 (New) A dispenser as in Claim 28, wherein the orifice is an eye.

Claim 74 (New) A dispenser as in Claim 28, wherein the orifice is a mouth.

Claim 75 (New) A method as in Claim 5, wherein the therapeutic gas consists of nitric oxide, the carrier gas is non-oxidizing, and the carrier gas and nitric oxide form a dilute mixture of nitric oxide.

Claim 76 (New) A method as in Claim 16, wherein the therapeutic gas consists of nitric oxide, the nitric oxide is present in a carrier gas, said carrier gas being inert and non-oxidizing, and wherein the carrier gas and nitric oxide form a dilute mixture of nitric oxide.

Claim 77 (New) A dispenser as in Claim 28, wherein the therapeutic gas consists of nitric oxide, the nitric oxide is present in a carrier gas, said carrier gas being inert and non-oxidizing, and wherein the carrier gas and nitric oxide form a dilute mixture of nitric oxide.

Claim 78 (New) A dispenser as in claim 35, wherein the container defines a first set of screw threads surrounding the sealing cap; the adjustable flow regulator comprises a collar

defining an orifice and a second set of screw threads surrounding the orifice which are adapted for mating with the first set of screw threads; said collar further defining a third set of screw threads surrounding the orifice, said third set of screw threads having a thread count of approximately 48 to 56 threads per inch; and wherein the head forms a fourth set of screw threads adapted for mating with the third set of screw threads, whereby axial translation of the head may be effected by mating and rotably adjusting the third and fourth set of screw threads, such that the needle may be inserted through and subsequently partially removed from the flow-regulating orifice in the sealing cap.

Claim 79 (New) A dispenser as in claim 36, wherein: the needle forms a first end adapted for perforating the sealing cap and a second end; the previously-formed orifice includes a valve seat and the second end of the needle is adapted to mate with the valve seat; the container defines a first set of screw threads surrounding the sealing cap; the adjustable flow regulator comprises a collar defining the previously-formed orifice and further defining a second set of screw threads surrounding the previously-formed orifice which are adapted for mating with the first set of screw threads; said collar further defining a third set of screw threads surrounding the previously-formed orifice; and wherein the head forms a fourth set of screw threads adapted for mating with the third set of screw threads, whereby axial translation of the head and needle may be effected by mating and rotably adjusting the third and fourth sets of screw threads; and the needle is positioned in the previously-formed orifice such that by rotatable adjustment of the third and fourth sets of screw threads the first end of the needle may be inserted through and subsequently adjusted relative to the previously-formed orifice in the collar and the second end of the needle may be mated with and subsequently lifted from the valve seat.

Claim 80 (New) A dispenser as in claim 49, wherein the container defines a first set of screw threads surrounding the sealing cap; the adjustable flow regulator comprises a collar defining an orifice and a second set of screw threads surrounding the orifice which are adapted for mating with the first set of screw threads; said collar further defining a third set of screw threads surrounding the orifice, said third set of screw threads having a thread count of between

approximately 48 to 56 threads per inch; and wherein the head forms a fourth set of screw threads adapted for mating with the third set of screw threads, whereby axial translation of the head may be effected by mating and rotably adjusting the third and fourth set of screw threads, such that the needle may be inserted through and subsequently partially removed from the flow-regulating orifice in the sealing cap.

Claim 81 (New) A dispenser as in claim 50, wherein: the needle forms a first end adapted for perforating the sealing cap and a second end; the previously-formed orifice includes a valve seat and the second end of the needle is adapted to mate with the valve seat; the container defines a first set of screw threads surrounding the sealing cap; the adjustable flow regulator comprises a collar defining the previously-formed orifice and further defining a second set of screw threads surrounding the previously-formed orifice which are adapted for mating with the first set of screw threads; said collar further defining a third set of screw threads surrounding the previously-formed orifice; and wherein the head forms a fourth set of screw thread adapted for mating with the third set of screw threads, whereby axial translation of the head and needle may be effected by mating and rotably adjusting the third and fourth sets of screw threads; and the needle is positioned in the previously-formed orifice such that by rotatable adjustment of the third and fourth sets of screw threads the first end of the needle may be inserted through and subsequently adjusted relative to the previously-formed orifice in the collar and the second end of the needle may be mated with and subsequently lifted from the valve seat.

Claim 82 (New) A dispenser as in claim 78, wherein the head comprises detents which permit selection of predefined flow rates.

Claim 83 (New) A dispenser as in claim 79, wherein the head comprises detents which permit selection of predefined flow rates.

Claim 84 (New) A dispenser as in claim 80, wherein the head comprises detents which permit selection of predefined flow rates.

Claim 85 (New) A dispenser as in claim 81, wherein the head comprises detents which permit selection of predefined flow rates.

Claim 86 (New) A dispenser as in claim 29, wherein the therapeutic agent is present in the container as a liquid.

Claim 87 (New) A dispenser as in claim 29, wherein the therapeutic agent is present in the container as a gas.

Claim 88 (New) A dispenser as in claim 53, wherein the therapeutic agent is present in the container as a liquid.

Claim 89 (New) A dispenser as in claim 53, wherein the therapeutic agent is present in the container as a gas.

Claim 90 (New) A dispenser as in claim 58, wherein the therapeutic agent is present in the container as a liquid.

Claim 91 (New) A dispenser as in claim 58, wherein the therapeutic agent is present in the container as a gas.

Claim 92 (New) A method as in claim 4, wherein the generating step further comprises mixing reagents, which, upon mixing, release carbon dioxide.

Claim 94 (New) A dispenser for delivering carbon dioxide gas, said dispenser comprising:
a container holding at least two reagents and comprising a frangible barrier, wherein the frangible barrier separates at least one reagent from the other reagents, and wherein the reagents upon mixing generate carbon dioxide;

and an outlet formed by the container through which the flow of the carbon dioxide gas is released, said outlet sealable with a human facial orifice.

Claim 95 (New) A dispenser as in claim 94, wherein the reagents comprise water, dry citric acid powder and sodium bicarbonate, and wherein the water is separated from the other reagents by the frangible barrier.

Claim 96 (New) A dispenser as in claim 95, wherein the frangible barrier comprises a plurality of microcapsules, and wherein each microcapsule contains water.

Claim 97 (New) A dispenser as in claim 34, wherein the head further comprises: a needle that perforates a sealing cap in the container to form an orifice of a preselected diameter and wherein the needle is axially translatable; a spring engaged with the needle that holds the needle in the orifice; a lever attached to the needle such that operation of the lever lifts the needle from the orifice and compresses the spring, whereby the gas is released through the outlet.

Claim 98 (New) A dispenser as in claim 97 wherein the diameter of the orifice is selected to permit a desired maximum flow rate.

Claim 99 (New) A dispenser as in claim 64 wherein the diameter of the orifice is selected to permit a desired maximum flow rate.

Claim 100 (New) A gas dispensing needle comprising:

a needle body having a penetrating tip and a proximal conical shaft with a first region near the penetrating tip and a second region removed from the penetrating tip adjacent to the first region, and

a flow passage between the second region of the shaft and an orifice; wherein the orifice is created in a container of pressurized gas by the penetrating tip and enlarged to a selected diameter by the second region of the conical shaft;

wherein the first region of the conical shaft defines a taper angle of greater than 25° and the second region of the conical shaft defines a taper angle of between about 2° and 6°.

Claim 101 (New) A gas dispensing needle as in claim 60 wherein the second region of the conical shaft defines a diameter having a maximum value of between 0.4 mm and 0.6 mm.

Claim 102 (New) A method for delivering a therapeutic gas to a person having a nasal mucous membrane, said method comprising:

generating a flow of a therapeutic gas; and

infusing the nasal mucous membrane with the flow of therapeutic gas; wherein the person substantially inhibits the passage of the therapeutic gas into the trachea and lung by limiting inhalation of the therapeutic gas.

Claim 103 (New) A method for delivering a therapeutic gas to a person having an oral mucous membrane, said method comprising:

generating a flow of a therapeutic gas; and

infusing the oral mucous membrane with the flow of therapeutic gas; wherein the person refrains from inhaling the therapeutic gas.

Claim 104 (New) A kit comprising:

A container holding a therapeutic agent; and

Instructions for use setting forth a method for delivering the therapeutic agent to a person from the container comprising:

generating a flow of the therapeutic agent in the form of a gas; and

directing the flow into a facial orifice of the person whereby a mucous membrane is infused with the gas; and

substantially inhibiting the passage of the gas into the trachea and lung of the person by limiting the person's inhalation of the therapeutic agent.

Claim 105 (New) A kit as in claim 54 wherein the instructions further set forth to direct the carbon dioxide to a nostril or mouth of the person while the person substantially inhibits the passage of the gas into the trachea and lung of the person by limiting the person's inhalation of the therapeutic agent.

2. Conclusion

Applicants submit that all claims are in condition for allowance and request early favorable action by the Examiner.

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